



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

9 4635d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

**WARNING LETTER
NWE-22-04W**

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 18, 2004

Michael A. Sousa
President
Sousa Lobster Co., Inc.
8 Seafood Way, Units 9-12
Boston, MA 02210

Dear Mr. Sousa:

We inspected your seafood processing facility, Sousa Lobster Co., Inc. located at 8 Seafood Way, Units 9-12, Boston, MA, on February 5, 9 and 13, 2004. We found that you have a serious deviation from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products processed there adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your cooked, ready-to-eat lobstermeat is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious deviation observed was as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for cooked, ready-to-eat lobstermeat you process at this location.

We may take further action if you do not promptly correct this above violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You should include in your response any documentation, such as your HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. We note that you also oversee the operations of Sousa Seafood, Inc., which is located at this same address. You are responsible for ensuring that all of your processing plants operate in compliance with the Act, the seafood HACCP regulations and the Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gail T. Costello', with a long horizontal flourish extending to the right.

Gail T. Costello
District Director
New England District Office